

AMENDMENTS TO THE CLAIMS

1. (Currently Amended) An apparatus comprising:
 - an expandable body having dimensions suitable for percutaneous delivery;
 - at least one delivery cannula having a lumen therethrough coupled to an exterior portion of the expandable body;
 - a needle disposed in the lumen of the at least one delivery cannula, the needle comprising a body portion having a protuberance thereon and a delivery end distal to the protuberance;
 - a first stop disposed in the lumen of the at least one delivery cannula at a position distal to the protuberance on the needle, the stop defining a diameter of the lumen less than an outer diameter of the needle at the protuberance; and
 - a second stop disposed in the lumen of the at least one delivery cannula at a position proximal to the protuberance on the needle, the second stop defining a diameter of the lumen less than an outer diameter of the needle at the protuberance.
2. (Currently Amended) The apparatus of claim 1, wherein the first stop comprises a sleeve having an outer dimension less than a dimension of the lumen of the at least one delivery cannula and a lumen therethrough having an inner dimension greater than an outer dimension of the needle at a point other than a point of the protrusion.
3. (Original) The apparatus of claim 1, wherein the protuberance comprises a sleeve coupled to the needle.
4. Cancelled.
5. (Currently Amended) The apparatus of claim ~~[[4]]~~ 2, wherein the sleeve comprises a first sleeve and the protuberance comprises a second sleeve coupled to the needle, the second sleeve having an outer dimension comprising a first cross-sectional shape of the at least one delivery cannula at a portion ~~proximal~~ distal to the second stop that is different from a ~~second cross-sectional shape of the delivery cannula proximal~~ distal to the second stop.

6. (Original) The apparatus of claim 5, wherein the first cross-sectional shape is other than circular.

7. (Original) The apparatus of claim 6, further comprising a ribbon disposed in the lumen and extending between the first stop and the second stop, the ribbon modifying a shape of the lumen, wherein the first cross-sectional shape comprises a shape corresponding to the modified shape of the lumen in the presence of the ribbon.

8. (Original) The apparatus of claim 1, further comprising:

a catheter body having a lumen therethrough, the lumen comprising a dimension at a distal end to contain the at least one delivery cannula and a dimension at a proximal end to contain the needle; and

a hub coupled to a proximal end of the catheter body,
wherein the needle extends through the hub and is maintained in a prescribed orientation.

9. (Original) The apparatus of claim 8, wherein the protuberance comprises a first protuberance, the apparatus further comprising:

a second protuberance coupled to the needle at a portion within the hub, the second protuberance having dimensions such that the needle may move a prescribed distance within the hub.

10. (Original) The apparatus of claim 9, wherein the coupling of the second protuberance to the needle defines the prescribed orientation of the needle.

11. (Original) The apparatus of claim 9, wherein the needle has a first axial orientation with respect to a distal end of the hub and a different second axial orientation with respect to a proximal end of the hub.

12. (Original) The apparatus of claim 11, wherein the difference between the first axial orientation and the second axial orientation defines an angle of at least 15°.

13. (Withdrawn) The apparatus of claim 1, wherein the expandable body comprises a first expandable body, the apparatus further comprising a second expandable body coupled to the first expandable body.

14. (Withdrawn) The apparatus of claim 13, wherein the at least one delivery cannula comprises at least one first delivery cannula coupled to the first expandable body and at least one second delivery cannula coupled to the second expandable body, each delivery cannula comprising a needle and a stop disposed in a lumen thereof.

15. (Withdrawn) The apparatus of claim 13, wherein the first expandable body and the second expandable body are in a series configuration.

16. (Withdrawn) The apparatus of claim 13, wherein the first expandable body and the second expandable body comprise different dimensions.

17. (Currently Amended) An apparatus comprising:
an expandable body having dimensions suitable for percutaneous delivery;
at least one delivery cannula having a lumen therethrough coupled to an exterior portion of the expandable body;
a needle disposed in the lumen of the at least one delivery cannula, the needle comprising a body portion having a protuberance thereon;
a first stop disposed in the lumen of the at least one delivery cannula at a position proximal to the protuberance on the needle, the stop defining a diameter of the lumen less than an outer diameter of the needle at the protuberance and
a second stop disposed in the lumen of the delivery cannula at a position distal to the protuberance on the needle, the second stop defining a diameter of the lumen less than an outer diameter of the needle at the protuberance.

18. (Original) The apparatus of claim 17, wherein the stop comprises a sleeve having an outer dimension less than a dimension of the lumen of the at least one delivery cannula and a

lumen therethrough having an inner dimension greater than an outer dimension of the needle at a point other than a point of the protrusion.

19. (Original) The apparatus of claim 17, wherein the protuberance comprises a sleeve coupled to the needle.

20. Cancelled.

21. (Currently Amended) The apparatus of claim ~~[[20]]~~ 18, wherein the sleeve comprises a first sleeve and the protuberance comprises a second sleeve coupled to the needle, the second sleeve having an outer dimension comprising a first cross-sectional shape of the at least one delivery cannula at a portion proximal to the second stop that is different from a second cross-sectional shape distal to the second stop.

22. (Original) The apparatus of claim 21, wherein the first cross-sectional shape is other than circular.

23. (Original) The apparatus of claim 22, further comprising a ribbon disposed in the lumen and extending between the first stop and the second stop, the ribbon modifying a shape of the lumen, wherein the first cross-sectional shape comprises a shape corresponding to the modified shape of the lumen in the presence of the ribbon, and the second cross-sectional shape comprises a circular shape.

24. (Original) The apparatus of claim 17, further comprising:

a catheter body having a lumen therethrough, the lumen comprising a dimension at a distal end to contain the at least one delivery cannula and a dimension at a proximal end to contain the needle; and

a hub coupled to a proximal end of the catheter body,
wherein the needle extends through the hub and is maintained in a prescribed orientation.

25. (Original) The apparatus of claim 24, wherein the protuberance comprises a first protuberance, the apparatus further comprising:

a second protuberance coupled to the needle at a portion within the hub, the second protuberance having dimensions such that the needle may move a prescribed distance within the hub.

26. (Original) The apparatus of claim 25, wherein the coupling of the second protuberance to the needle defines the prescribed orientation of the needle.

27. (Original) The apparatus of claim 24, wherein the needle has a first axial orientation with respect to a distal end of the hub and a different second axial orientation with respect to a proximal end of the hub.

28. (Original) The apparatus of claim 27, wherein the difference between the first axial orientation and the second axial orientation defines an angle of at least 15°.

29. (Withdrawn) The apparatus of claim 17, wherein the expandable body comprises a first expandable body, the apparatus further comprising a second expandable body coupled to the first expandable body.

30. (Withdrawn) The apparatus of claim 29, wherein the at least one delivery cannula comprises at least one first delivery cannula coupled to the first expandable body and at least one second delivery cannula coupled to the second expandable body, each delivery cannula comprising a needle and a stop disposed in a lumen thereof.

31. (Withdrawn) The apparatus of claim 29, wherein the first expandable body and the second expandable body are in a series configuration.

32. (Withdrawn) The apparatus of claim 29, wherein the first expandable body and the second expandable body comprise different dimensions.

33. (Currently Amended) An apparatus comprising:
an expandable body having dimensions suitable for percutaneous delivery;
at least one delivery cannula coupled to an exterior portion of the expandable body comprising a plication region defined in response to an expansion of the expandable body; and
a sheath ring circumferentially disposed about the at least one delivery cannula and the ~~catheter~~ expandable body proximally adjacent the plication region.

34. (Original) The apparatus of claim 33, wherein the expandable body comprises a balloon and the balloon is coupled at a proximal end to an inflation cannula.

35. (Original) The apparatus of claim 34, wherein the balloon comprises a proximal portion and a working length, the working length having a diameter capable of being expanded in one condition to an inner diameter of a blood vessel at a point of interest, the proximal portion comprising at least a portion having a diameter less than the diameter of the working length at the one condition, and where the at least one delivery cannula is coupled to a proximal portion of the balloon.

36. (Original) The apparatus of claim 35, wherein the at least one delivery cannula comprises a distal end and the proximal portion of the balloon has a length defined from a proximal end to a distal end and the distal end of the at least one delivery cannula is disposed at a point that is less than or equal to the length of the proximal portion of the balloon.

37. (Original) The apparatus of claim 34, further comprising a transport cannula disposed about a portion of the inflation cannula and a portion of the at least one delivery cannula proximal to the sheath ring.

38. (Original) The apparatus of claim 37, wherein the at least one delivery cannula comprises a first delivery cannula and a different second delivery cannula and wherein each of the first delivery cannula and the second delivery cannula comprises a center axis extending in similar directions in different planes and a distance between the center axes within the sheath ring is less than a distance between the center axes at a point proximal to the sheath ring.

39. (Original) The apparatus of claim 37, wherein a distal end of the transport cannula is separated from the sheath ring by at least one millimeter.
40. (Original) The apparatus of claim 34, wherein the at least one delivery cannula is coupled to the balloon by an adhesive.
41. (Original) The apparatus of claim 40, wherein the adhesive comprises a cyanoacrylate material.
42. (Original) The apparatus of claim 33, further comprising:
a needle disposed in a lumen of the at least one delivery cannula;
a catheter body having a lumen therethrough, the lumen comprising a dimension at a distal end to contain the at least one delivery cannula and a dimension at a proximal end to contain the needle; and
a hub coupled to a proximal end of the catheter body,
wherein the needle extends through the hub and is maintained in a prescribed orientation within the hub.
43. (Original) The apparatus of claim 42, further comprising a protuberance coupled to the needle at a portion within the hub, the protuberance having dimensions such that the needle may move a prescribed distance within the hub.
44. (Original) The apparatus of claim 43, wherein the coupling of the protuberance to the needle defines the prescribed orientation of the needle.
45. (Original) The apparatus of claim 42, wherein the needle has a first axial orientation with respect to a distal end of the hub and a different second axial orientation with respect to a proximal end of the hub.

46. (Original) The apparatus of claim 45, wherein the difference between the first axial orientation and the second axial orientation defines an angle of at least 15°.

47. (Withdrawn) The apparatus of claim 34, wherein the balloon comprises a first balloon, the expandable body further comprises at least a second balloon coupled to the first balloon.

48. (Withdrawn) The apparatus of claim 47, wherein the at least one delivery cannula comprises at least one first delivery cannula coupled to the first balloon and at least one second delivery cannula coupled to the second balloon.

49. (Withdrawn) The apparatus of claim 47, wherein the first balloon and the second balloon are in a series configuration.

50. (Withdrawn) The apparatus of claim 47, wherein the first balloon and the second balloon comprise different dimensions.

51. (Currently) An apparatus comprising:

an expandable body having dimensions suitable for percutaneous delivery;

at least one delivery cannula having a lumen therethrough coupled to an exterior portion of the expandable body;

a needle disposed in the lumen of the at least one delivery cannula; and

a sleeve coupled to an exterior of the needle, the sleeve having an outer dimension comprising a first shape corresponding to a shape of the lumen of the delivery cannula;

a catheter body having a lumen therethrough, the lumen comprising a dimension at a distal end to contain the at least one delivery cannula;

a hub coupled to a proximal end of the catheter body, wherein the needle extends proximally through the hub and is maintained in a prescribed orientation; and

a protuberance coupled to the needle at a portion within the hub, the protuberance having dimensions such that the needle may move a prescribed distance within the hub.

52. (Original) The apparatus of claim 51, wherein a first portion of the lumen of the at least one delivery cannula has a dimension corresponding to a shape of the sleeve and a second portion of the at least one cannula has a different shape.

53. (Original) The apparatus of claim 51, further comprising a stop disposed in the lumen of the at least one delivery cannula at a position proximal to the sleeve.

54. Cancelled.

55. Cancelled.

56. (Currently Amended) The apparatus of claim ~~[[55]]~~ 51, wherein the coupling of the protuberance to the needle defines the prescribed orientation of the needle.

57. (Currently Amended) The apparatus of claim ~~[[54]]~~ 51, wherein the needle has a first axial orientation with respect to a distal end of the hub and a different second axial orientation with respect to a proximal end of the hub.

58. (Original) The apparatus of claim 56, wherein the difference between the first axial orientation and the second axial orientation defines an angle of at least 15°.

59. (Withdrawn) The apparatus of claim 51, wherein the expandable body comprises a first expandable body, the apparatus further comprising a second expandable body coupled to the first expandable body.

60. (Withdrawn) The apparatus of claim 59, wherein the at least one delivery cannula comprises at least one first delivery cannula and at least one second delivery cannula coupled to the second expandable body, each delivery cannula comprising a needle comprising a sleeve coupled thereto.

61. (Withdrawn) The apparatus of claim 51, wherein the first expandable body and the second expandable body are in a series configuration.

62. (Withdrawn) The apparatus of claim 61, wherein the first expandable body and the second expandable body comprise different dimensions.

63. (Original) An apparatus comprising:

a first cannula body having dimensions suitable for percutaneous delivery through a catheter cannula; and

a second cannula body comprising a superelastic material coupled to the first cannula body,

wherein the first cannula body and the second cannula body define a continuous lumen therethrough.

64. (Original) The apparatus of claim 63, wherein the superelastic material of the second cannula body comprises a nickel-titanium alloy.

65. (Original) The apparatus of claim 63, wherein the first cannula body comprises a material such that the first cannula body has sufficient column strength to be pushable in a vasculature of a patient without buckling.

66. (Original) The apparatus of claim 64, wherein the second cannula body comprises a first end and a second end, the first end coupled to the first cannula body and the second end comprising an end suitable for puncturing tissue.

67. (Original) The apparatus of claim 63, further comprising:

a catheter cannula having a lumen therethrough, the lumen comprising a dimension to contain the first cannula body; and

a hub coupled to a proximal portion of the catheter cannula,

wherein the first cannula body extends through the hub and is maintained in a prescribed orientation within the hub.

68. (Original) The apparatus of claim 67, further comprising a protuberance coupled to the first cannula body at a portion within the hub, the protuberance having dimensions such that the first cannula body may move a prescribed distance within the hub.

69. (Original) The apparatus of claim 68, wherein the coupling of the protuberance to the first cannula body defines the prescribed orientation of the first cannula body .

70. (Original) The apparatus of claim 69, wherein the first cannula body has a first axial orientation with respect to a distal end of the hub and a different second axial orientation with respect to a proximal end of the hub.

71. (Original) The apparatus of claim 70, wherein the difference between the first axial orientation and the second axial orientation defines an angle of at least 15°.

72. (Currently Amended) An apparatus comprising:

a catheter cannula having a length suitable for tracking through a portion of a vasculature and a dimension suitable for percutaneous delivery;

at least one needle extending through a portion of the catheter cannula and having a distal end; and

a hub coupled to a proximal portion of the catheter cannula; and
a protuberance coupled to the needle; the at least one needle associated with the hub such that a proximal or a distal movement of the at least one needle within the hub is limited by contact between the protuberance and the hub.

73. (Currently Amended) The apparatus of claim 72, wherein a proximal portion of the at least one needle is associated with the hub according to a prescribed radial orientation.

74. (Original) The apparatus of claim 73, wherein the at least one needle comprises a first needle and a second different needle.

75. (Original) The apparatus of claim 73, wherein the hub comprises a first track and a second track, the first track having dimensions suitable to accommodate the first needle therein and the second track having dimensions suitable to accommodate the second needle therein.

76. (Original) The apparatus of claim 75, wherein the first track comprises a first portion and a second portion, wherein the first portion has a dimension greater than the second dimension such that the portion of the first needle comprising the protuberance may advance in distal or proximal direction within the first portion.

77. (Original) The apparatus of claim 76, wherein the second portion of the first track has a dimension less than a dimension of the protuberance.

78. (Currently Amended) An apparatus comprising:

a balloon catheter comprising a cannula having a length suitable for tracking through a portion of a vasculature and an inflatable balloon coupled to the distal end of the catheter;

at least one needle having a length suitable for delivering a distal end to the balloon with a proximal end outside the vasculature, the needle comprising a first protuberance on a distal portion that increases an outer diameter of the at least one needle at a point of the first protuberance;

a hub coupled to a proximal portion of the cannula and retaining the at least one needle according to a prescribed radial orientation by a second protuberance on a proximal portion of the needle; and

at least one needle cannula comprising a proximal portion and a distal portion, the needle cannula having a lumen suitable for containing the at least one needle, wherein a distal point of the lumen of the at least one catheter cannula comprises a diameter less than an exterior diameter of the at least one needle at the point of the first protuberance.

79. (Original) The apparatus of claim 78, further comprising at least one delivery cannula different from the at least one needle cannula and coupled to a proximal portion of the balloon, and having a length dimension suitable for containing at least a portion of the length of the at

least one needle, wherein proximally to distally, the at least one needle is disposed through the at least one needle cannula and the at least one delivery cannula.

80. (Original) The apparatus of claim 79, further comprising a sheath ring disposed about the at least one delivery cannula proximal to a plication region of the at least one delivery cannula defined in response to an inflation of the balloon.

81. (Currently Amended) The apparatus of claim 80, wherein the point of the lumen of the at least one catheter cannula comprising a diameter less than an exterior diameter of the at least one needle at the point of the first protuberance is a first point, the lumen of the at least one catheter cannula comprising a second point comprising a diameter less than an exterior diameter of the at least one needle at the point of the first protuberance, and wherein a distance between the first point and the second point defines a travel distance for the at least one needle.

82. (Currently Amended) The apparatus of claim 78, wherein a cross-sectional shape of at least one of the first protuberance and the needle at the point of the first protuberance is different than a cross-sectional shape of the lumen of the catheter cannula at a point at least one of proximal or distal to the point of the first protuberance.

83. (Currently Amended) The apparatus of claim 78, wherein ~~the protuberance of the at least one needle comprises a first protuberance, and the at least one needle comprises a second protuberance and~~ the at least one needle is associated with the hub such that a proximal or a distal movement of the at least one needle within the hub is limited by contact between the second protuberance and the hub.

84. (Original) The apparatus of claim 78, wherein a distal portion of the at least one needle comprises a superelastic material.

85. (Currently Amended) An apparatus comprising:
an expandable body having dimensions suitable for percutaneous delivery;

at least one delivery cannula having a lumen therethrough coupled to an exterior portion of the expandable body;

a needle comprising a proximal portion and a distal portion disposed in the lumen of the
at least one delivery cannula and having a defined travel path in a direction defined between a
proximal and distal end of the at least one delivery cannula wherein the distal portion has an
inside diameter less than an inside diameter of the proximal portion.

86. Cancelled.

87. (Currently Amended) The apparatus of claim [[86]] 85, wherein the distal portion is coupled to the proximal portion.

88. (Withdrawn) The apparatus of claim 87, wherein the distal portion has a first beveled end and a second beveled end, wherein the first beveled end is beveled in a direction different than a direction of the second beveled end.

89. (Currently Amended) The apparatus of claim [[86]] 85, wherein the distal portion has an outside diameter less than an outside diameter of the proximal portion.

90. (Original) The apparatus of claim 89, wherein a transition point between the proximal portion and the distal portion defines a step.

91. (Withdrawn) The apparatus of claim 89, wherein a transition between the proximal portion and the distal portion tapers in diameter.

92. (Currently Amended) A method comprising:

positioning a catheter assembly comprising at least one needle delivery device disposed in
an at least one delivery cannula, the at least one delivery cannula having an exit end;
maintaining a prescribed orientation of the at least one needle delivery device at a
proximal end;

maintaining a prescribed orientation of the at least one needle delivery device at a distal end; and

~~modifying the shape of the catheter assembly to modify the orientation of the exit end of the at least one delivery cannula at a region of interest; and~~

advancing the at least one needle delivery device beyond the exit end of the at least one delivery cannula ~~according to a controlled orientation of the at least one delivery device within the at least one delivery cannula.~~

93. (Original) The method of claim 92, wherein the catheter assembly comprises an expandable structure and modifying the shape of the catheter assembly comprises expanding the expandable structure from a first dimension to a greater second dimension.

94. (Original) The method of claim 92, further comprising, after advancing the at least one needle delivery device, delivering at least one treatment agent.

95. (Currently Amended) The method of claim 92, wherein advancing the at least one needle delivery device comprises modifying the shape of the catheter assembly to modify the orientation of the exit end of the at least one delivery cannula at a region of interest. ~~maintaining a prescribed orientation of the at least one needle delivery device at a proximal end.~~

96. Cancelled.